

REQUEST FOR NEW OFFICE ACTION
US APPLN. NO. 10/807,023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: CHEN, S., et. al.) Art Unit: 1654
Serial No.: 10/807,023) Examiner: Kosar, Andrew D.
Conf. No.: 2248
Filed: 03/23/2004
For: Pharmaceutical Compositions for Hepatitis C Viral Protease Inhibitors
Docket No.: 9/279

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR NEW OFFICE ACTION

Sir:

This is in response to the Office Action dated February 22, 2006, in the above-identified application.

Applicants hereby respectfully request a new non-final Office Action because it is believed that the Office Action dated February 22, 2006, was incomplete. Specifically, at pages 7 to 10 of the Office Action, Claims 1-27 are rejected under 35 USC §103 as being obvious over Chen (U.S. 6,828,301), in view of Patel (US 2001/0024658) and Tsantrizos (U.S. 6,608,027). The obviousness argument is basically premised on the argument that although Chen does not teach the instantly recited bases being used in their disclosed composition, this addition of base to the composition would have been obvious in light of the other art cited. See pages 9-10 of the Office Action.

In the context of a conclusion of *prima facie* obviousness, any comparative evidence presented in the application as filed to demonstrate unexpected results of the invention is evidence that must be considered. See MPEP 716.01(a). Such comparative evidence was presented in the present specification in the Examples at pages 38-41, and data regarding improved chemical stability discussed at page 40 and shown in Tables 1a and 1b, and Figures 1 and 2. In fact, comparative Formulation # 1 in the specification appears to be identical with Formulation #6A of Chen (disclosed in Chen at col. 38, lines 50-62). The comparative experimentation clearly show the improved chemical stability for the formulations of the present invention as compared to the formulation of Chen (not containing sodium hydroxide base) and is believed to

REQUEST FOR NEW OFFICE ACTION
US APPLN. NO. 10/807,023

demonstrate the non-obviousness of the present invention. This comparative data was apparently either not considered by the Examiner or, if the Examiner did consider it, it was not explained in the Office Action why the data was not sufficient to overcome the obviousness rejection. Applicants therefore believe that the Office Action was incomplete for failing to discuss the comparative experimentation present in the application as filed, and believe therefore that a new, non-final office action (having a restarted response period) should be issued for the present application, which office action specifically addresses the comparative experimentation present in the application as filed.

In view of the above remarks, Applicants respectfully request a new and complete non-final office action. If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

/Philip I. Datlow/

Philip I. Datlow
Attorney for Applicant(s)
Reg. No. 41,482

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel: (203) 798-4542
Date: March 16, 2006